

OCT 11 1996

K962761

I.510(K) SUMMARY

Submitted By:

April Lavender
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
July 12, 1996

Device:

Trade Name: Reigel Tunneling Device
Common/Usual Name: Tunneler, Catheter Passer
Proposed Classification: Shunt System Implantation Instrument
21 CFR 882.4545 (84GYK), Class I

Predicate Devices:

The Reigel Tunneling Device is similar in terms of intended use, materials of construction, and technological characteristics to predicate devices reviewed as instruments used to place cerebrospinal fluid shunt systems.

Device Description:

The Reigel Tunneling Device is used for tunneling and passing shunt components under the skin for the placement of cerebrospinal fluid shunts from the head to the abdomen. The device is supplied sterile. The materials comprising the device have an established history of use in medical product manufacturing.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently manufactured and marketed by COOK INCORPORATED. This device is similar with respect to indications for use, materials and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.